DEPARTMENT OF HEALTH AND HUMAN SERVICES

950542

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

October 20, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 05-03

Jeffrey D. Wendler, DVM, Partner
Ron Aardema, Partner
Donald Aardema, Jr., Partner
Michael Aardema, Partner
St. Bridget Dairy, LOP
2306 East 3600 South
Wendell, Idaho 83355

WARNING LETTER

Dear Sirs:

On July 14, 2004, our investigator inspected your dairy farm located at 194 West 400 South, Jerome, Idaho. This inspection confirmed that you offered an animal for sale for slaughter as food in violation of Section 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (the Act). You also caused an animal drug to become adulterated because the drug was used in a manner that does not conform to its approved uses or the extralabel use regulations in Title 21, Code of Federal Regulations, Part 530 (21 CFR Part 530). This caused the animal drug to be unsafe under Section 512(a) of the Act and therefore adulterated within the meaning of Section 501(a)(5) of the Act. You can find the Act and associated regulations on the Internet through links on FDA's web page www.fda.gov.

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act. You sold a dairy cow on or about May 24, 2004, identified with back tag # [redacted] Ear Tag # [redacted] and further identified as USDA FSIS lab report # 433590, for slaughter as human food to [redacted] USDA analysis of tissue samples collected from that animal identified the presence of penicillin in the kidney at 0.10 parts per million (ppm) and sulfadimethoxine in the liver at 0.18 ppm. The tolerance for penicillin in uncooked edible tissues of cattle is 0.05 ppm (21 CFR 556.510) and the tolerance for sulfadimethoxine in uncooked edible tissues of cattle is 0.1 ppm (21 CFR 556.640). Because your extralabel use of penicillin and sulfadimethoxine resulted in the presence of residues above the established tolerances, use of the drug was not in compliance with extralabel use regulations (21 CFR 530.11(d)).

The investigation also determined that you adulterated two (2) animal drugs within the meaning of Section 501(a)(5) of the Act when you failed to use the drugs in conformance with the extralabel use regulations at 21 CFR Part 530. Specifically, you used the drugs penicillin and sulfadimethoxine in excess of the labeled dosage and failed to withhold the animal from slaughter for an appropriate withdrawal period. Extralabel drug use is permitted only in conformance with all criteria set forth in 21 CFR Part 530, including that there may be no residue above established tolerance levels.

Further, as the veterinarian for this dairy, Dr. Wendler failed to label the penicillin and sulfadimethoxine he prescribed and dispensed for extralabel use with labeling information adequate to assure the safe and proper use of the drugs, including the dosage, frequency, route of administration, duration of therapy, and the specified withholding time, as required in 21 CFR 530.12.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal to be slaughtered into food for human consumption where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

The above is not intended to be an all-inclusive list of violations. As a producer of animals that are offered for use as food, you are responsible for ensuring that your overall operations and the food you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

Within fifteen (15) working days of the receipt of this letter, please advise this office of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed.

Please send your written reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, WA 98021-4421. If you have any questions regarding this letter, please contact Ms. Althar at (425) 483-4940.

Sincerely,

Charles M. Breen
District Director